

DETAILED ACTION

Claims 2-5, 10-14, 16, 24-28, 36, 38, 41-44, 49 and 57-76 have been canceled.

Claims 1, 6-9, 15, 17-23, 29-35, 37, 39, 40, 45-48 and 50-56 remain pending.

Election/Restrictions

The species election has been withdrawn in view of the amendment because the claims all relate to nucleotides 54755-55810 of SEQ ID NO: 1 – a 0.96 kb fragment.

This application contains claims 45-48, 50-56 drawn to an invention nonelected with traverse in the reply filed on 4-17-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144)

See MPEP § 821.01. Claims 45-48, 50-56 remain withdrawn.

Claims 1, 6-9, 15, 17-23, 29-35, 37 and 39 are under consideration as they relate to the claims as amended, which all relate to nucleotides 54755-55810 of SEQ ID NO: 1 – a 0.96 kb fragment.

Applicant's arguments filed 11-19-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

When referencing the original specification, please use the original page and line numbers. Do not use the page and paragraph numbers of the Published Application.

Claim Objections

Claims 1 and 19 are objected to because "is not a sequence that operably linked to an s-ship promoter in nature" is grammatically incorrect. The phrase can be simplified to --is not operably linked to an s-ship promoter in nature--.

Claim 30 is objected to because it appears to be inadvertently dependent upon claim 1 instead of claim 29.

Claim 35 is objected to because the host cell must be isolated. Please insert "isolated" before --host cell--.

Specification

The title has been changed to more closely reflect the subject matter being examined.

Claim Rejections - 35 USC § 112

New Matter

The rejection regarding the limitation of "i) nucleotides 54807 to 61006 but lacking nucleotides 57109 to 57944 or 2)..." in claim 8 has been withdrawn in view of pg 2, line 2.

The phrase "wherein said heterologous nucleic acid sequence is not a sequence that operably [sic] linked to an s-ship promoter in nature" in claims 1 and 19 as amended has support on pg 7, lines 12-20.

Claims 1, 6-9, 19-23, 30, 35, 37 and 39 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase “to be transcribed” in claims 1 and 19 is new matter. Nowhere do paragraphs 23, 66 or 71 of the Published Application qualify a heterologous nucleic acid sequence as one “to be transcribed”. The species within the genus was not explicitly or implicitly contemplated by applicants in the specification as originally filed.

Indefiniteness

The rejection of claims 15, 17 and 18 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of the amendment to claim 15.

Double Patenting

The objection to claim 10 under 37 CFR 1.75 as being a substantial duplicate of claim 9 has been withdrawn because claim 10 has been canceled.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 15, 17-21, 23 and 29-32 under 35 U.S.C. 102(b) as being anticipated by Birren (AC102564 in GenEmbl database, Nov. 23, 2001) has been withdrawn because Birren did not teach the nucleic acid sequence encoding nucleotides 54755-55810 of SEQ ID NO: 1 (see 6th hit of AC102564 in GenEmbl database, filed by direct submission on Nov. 23, 2001, Whitehead institute/MIT Center for Genome Research) was operably linked to a heterologous nucleic acid sequence that is not a operably linked to an s-shp promoter in nature as now claimed.

Claim Rejections - 35 USC § 103

Claims 1, 15, 17-23, 29-35, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren (cited above) in view of Alt (US Patent 5,583,278).

Alt taught a plasmid comprising a promoter operably linked to a heterologous nucleic acid sequence that is not operably linked to the promoter in nature. The coding region of the protein is modified by inserting a marker protein (col. 10, lines 8-24), which is equivalent to claim 15. The plasmid was put into embryonic stem cells, which is equivalent to claims 35-40. Alt did not teach the promoter was the s-ship promoter claimed.

However, nucleic acid sequence encoding nucleotides 54755-55810 of SEQ ID NO: 1 (see 6th hit of AC102564 in GenEmbl database, filed by direct submission on Nov. 23, 2001, Whitehead institute/MIT Center for Genome Research), the s-ship promoter, was disclosed by Birren.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to make a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter (wherein the heterologous nucleic acid sequence was not linked to the promoter in nature) as taught by Birren, wherein the promoter was the s-ship promoter disclosed by Birren. Those of ordinary skill in the art at the time of filing would have been motivated to use the s-ship promoter as the promoter to express the protein in ES cells.

Applicants argue those of skill did not know the sequence of Birren was an s-ship promoter. Applicants' argument is not persuasive. Wolf (Genomics, Oct. 1, 2000, Vol. 69, No. 1, pg 104-112) and Tu (Blood, 2001, Vol. 98, pg 2028-2038) taught the promoter region of the s-ship gene, which includes the sequence taught by Birren. It is also noted that claim 15 merely requires the nucleic acid comprises the promoter and a marker sequence, and claim 29 merely requires a vector comprising the promoter; claims 15 and 29 are not limited to combining a "heterologous" segment with the s-ship promoter.

Claims 1, 15, 17-23, 29-35, 37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren (cited above) in view of Cooke (US Patent 5,428,070).

Cooke taught hematopoietic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter. The coding region of the protein is modified by inserting a marker protein (col. 6, lines 33-55). Alt did not teach the promoter was the s-ship promoter claimed.

However, the s-ship promoter was disclosed by Birren.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to transfect hematopoietic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter as taught by Birren, wherein the promoter was the s-ship promoter disclosed by Birren. Those of ordinary skill in the art at the time of filing would have been motivated to use the s-ship promoter as the promoter to express the protein in ES cells.

Applicants' response filed fails to address this rejection separately. Applicants are reminded that each rejection must have its own heading and arguments. Failure to do so is considered non-responsive. Applicants' arguments may be copied, referenced or repeated under each new heading; however, arguing obviousness rejections together is not an option. A "non-responsive letter" should have been sent out because of applicants' error; however, the instant office action has been sent instead to expedite prosecution. Applicants' arguments regarding Birren are addressed above.

Applicants have received a search for 3 segments of the 11.5 kb fragment and a search for the 9.6 kb fragment. The fragments listed in claims 6-10 have not been searched. It remains unclear whether claims 6-10 are free of the prior art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

SEQ ID NO: 1 of Krystal (US Patent 6,218,162), starting at nucleotide 800, is the same as nucleotides 55668-55810 of SEQ ID NO: 1.

Lucas (Blood, 1999, Vol. 93, No. 6, pg 1922-1933) also taught nucleotides 55668-55810 of SEQ ID NO: 1.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Art Unit: 1632

If attempts to reach the examiner are unsuccessful, the examiner's supervisor,
Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner